REMARKS

Claims 1-23 were originally filed and were subject to a Restriction Requirement.

In the Restriction Requirement, the Examiner requested Applicants to elect one of the following inventions:

Group I (Claims 1, 2, and 15) drawn to an isolated polypeptide of a specific SEQ ID NO: and a pharmaceutical composition comprising said polypeptide,

Group II (Claims 3-6, 8, 10, and 11) drawn to an isolated polynucleotide of a specific SEQ ID NO:, fragments thereof, a transformed host cell and a method of producing a polypeptide,

Group III (Claim 7) drawn to a transgenic organism comprising a polynucleotide of a specific SEQ ID NO:,

Group IV (Claim 9) drawn to an antibody which specifically bind [sic: binds] to a polypeptide of a specific SEQ ID NO:,

Group V (Claims 12-14) drawn to a method for detecting a target polynucleotide comprising a specific SEQ ID NO:,

Group VI (Claim 16) drawn to a method comprising administering a pharmaceutical composition comprising a polypeptide of a specific SEQ ID NO:,

Group VII (Claim 17) drawn to a method for screening an agonist of a polypeptide of a specific SEQ ID NO:,

Group VIII (Claims 18 and 19) drawn to a pharmaceutical composition comprising an agonist of a polypeptide of a specific SEQ ID NO: and a method of using said composition,

Group IX (Claim 20) drawn to a method for screening an antagonist of a polypeptide of a specific SEQ ID NO:,

Group X (Claims 21 and 22) drawn to a pharmaceutical composition comprising an antagonist of a polypeptide of a specific SEQ ID NO: and a method of using said composition, and

Group XI (Claim 23) drawn to a method for screening a compound which alters expression

of a polynucleotide of a specific SEQ ID NO:.

Claims 16-22 have been canceled. Claims 24-30 have been added. Therefore, Claims 1-15 and 23-30 are pending.

Applicants hereby elect to prosecute the claims of Group II (Claims 3-6, 8, 10, and 11), as well as newly added Claims 24, 28, and 30 (directed to polynucleotides) and Claim 25 (directed to a method of producing a polypeptide), with traverse. In addition, in response to the "restriction requirement" to elect a particular SEQ ID NO:, Applicants provisionally elect the portion of the claims directed to SEQ ID NO:1 (polypeptide) and SEQ ID NO:9 (polynucleotide), also with traverse.

Applicants traverse both requirements on the following grounds:

Applicants first submit that the invention encompassed by the claims of Group I (Claims 1, 2, and 15, drawn to polypeptides) could be examined at the same time as the invention encompassed by the claims of Group II without undue burden on the Examiner. For example, a search of the prior art to determine the novelty of the polynucleotides of Group II would provide information regarding the novelty of the polypeptides of Group I.

Applicants second submit that Claims 12-14 (Group V), newly added Claim 26, Claim 23 (Group XI) and newly added Claims 27 and 29 are method of use claims which should be examined together with the polynucleotides of Group II, per the Commissioner's Notice in the Official Gazette of March 26, 1996, entitled "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)" which sets forth the rules, upon allowance of product claims, for rejoinder of process claims covering the same scope of products.

Accordingly, because the search required to identify prior art relevant to the claims of Groups I, II, V, and XI, as well as newly added Claims 24-30 would substantially overlap, Applicants respectfully submit that examination of Claims 1-6, 8, 10-15, and 23-30 would pose no undue burden. Thus, Applicants request reconsideration and withdrawal of the Restriction Requirement and examination of Claims 1-6, 8, 10-15, and 23-30.

However, in addition, Applicants also traverse this restriction requirement insofar as it is, in effect, a requirement for election of species as between elements in Markush groups (those elements being, respectively, SEQ ID NO:1-8 with respect to the polypeptides, and SEQ ID NO:9-16 with respect to the polynucleotides). The Examiner's attention is directed to the Patent Office's own requirements for Markush practice, set forth in the 8th edition of the M.P.E.P. (August 2001) at § 803.02 regarding restriction requirements in Markush-type claims:

> PRACTICE RE MARKUSH-TYPE CLAIMS
>
> If the members of the Markush group are **sufficiently few in number or so closely related** that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction.
>
> Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas,* 580 F.2d 461, 198 USPQ 334 (CCPA 1978), **it is improper for the Office to refuse to examine that which applicants regard as their invention**, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, **unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.**
>
> This subsection deals with Markush-type generic claims which include a plurality of alternatively usable substances or members. In most cases, a recitation by enumeration is used because there is no appropriate or true generic language. A Markush-type claim can include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s). In applications containing claims of that nature, **the examiner may require a provisional election of a single species** prior to examination on the merits. The provisional election will be given effect in the event that the Markush-type claim should be found not allowable. Following election, the Markush-type claim will be

examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable over the prior art, examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration.

As an example, in the case of an application with a Markush-type claim drawn to the compound C-R, wherein R is a radical selected from the group consisting of A, B, C, D, and E, the examiner may require a provisional election of a single species, CA, CB, CC, CD, or CE. The Markush-type claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the nonelected species would be held withdrawn from further consideration. As in the prevailing practice, a second action on the rejected claims would be made final.

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a *non-elected species,* the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry. [emphasis added]

As can be seen from the above, it is clear that the present Restriction Requirement does not meet the Patent Office's own requirements.

The Examiner alleged that "[i]t is noted that this is not a species election for the elected group as each of the sequences SEQ ID NO:1-16 are also patentably distinct." (Office Action, page 5.)

However, is first noted that if the number of "members of the Markush group are

sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to **independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction.**" Withdrawal of the restriction requirement, at least as between a reasonable number of the specific sequences each in the claims is required on that basis alone.

Second, **it is improper for the Office to refuse to examine that which applicants regard as their invention**, unless the subject matter in a claim lacks unity of invention. The polynucleotides of the present invention, as well as the polypeptides they encode, share a common utility in, for example, toxicology studies based on expression profiling.

Third, even if the claims could be considered to be "Markush-type generic claims which include a plurality of alternatively usable substances or members," it is further noted that the M.P.E.P states that "A Markush-type claim can include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s). In applications containing claims of that nature, **the examiner may require a provisional election of a single species** prior to examination on the merits." This clearly applies in the present case.

Finally, Examiner's attention is directed to the M.P.E.P. at § 803.04 (Restriction - Nucleotide Sequences, EXAMPLES OF NUCLEOTIDE SEQUENCE CLAIMS) which states:

> Applications claiming more than ten individual independent and distinct nucleotide sequences in alternative form, such as set forth in example (A), will be subject to a restriction requirement. Only the ten nucleotide sequences selected in response to the restriction requirement and any other claimed sequences which are patentably indistinct therefrom will be examined.
>
> Applications claiming only a combination of nucleotide sequences, such as set forth in example (B), will generally not be subject to a restriction requirement. The presence of one novel and nonobvious sequence within the combination will render the entire combination allowable. The combination will be searched until one

> nucleotide sequence is found to be allowable. The order of searching will be chosen by the examiner to maximize the identification of an allowable sequence. If no individual nucleotide sequence is found to be allowable, the examiner will consider whether the combination of sequences taken as a whole renders the claim allowable.

The instant application claims eight sequences and the claims examined clearly should not be limited by an election of only a single sequence under the guidelines set forth in the M.P.E.P. at § 803.04.

Therefore, it is respectfully submitted that, upon searching and examining SEQ ID NO:1 (polypeptide) and SEQ ID NO:9 (polynucleotide) and finding no prior art over which SEQ ID NO:1 and SEQ ID NO:9 can be rejected, the Examiner must extend the search of the Markush-type claim to include the non-elected species.

Applicants expressly reserve the right to prosecute non-elected subject matter in subsequent divisional applications.

CONCLUSION

In light of the above amendments and remarks, Applicants submit that the present application is fully in condition for allowance, and request that the Examiner withdraw the outstanding rejections. Early notice to that effect is earnestly solicited.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact Applicants' Agent at (650) 845-4646.

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. **09-0108. This form is enclosed in duplicate.**

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION:

IN THE CLAIMS:

Claims 16-22 have been canceled.

Claims 4 and 23 have been amended as follows.

Claims 24-30 have been added.

4. (Once Amended) An isolated polynucleotide of claim 3 comprising a polynucleotide sequence selected from the group consisting of SEQ ID NO:9-16.

23. (Once Amended) A method of [for] screening a compound for effectiveness in altering expression of a target polynucleotide, wherein said target polynucleotide comprises a sequence of claim 4, the method comprising:

a) exposing a sample comprising the target polynucleotide to a compound, under conditions suitable for the expression of the target polynucleotide, [and]

b) detecting altered expression of the target polynucleotide, and

c) comparing the expression of the target polynucleotide in the presence of varying amounts of the compound and in the absence of the compound.